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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,164	04/04/2005	Susanne Binder	34157-707.831	5602

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EXAMINER	
KIM, TAEYOON	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
05/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,164	BINDER ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42,45-49 and 53-61* is/are pending in the application.

4a) Of the above claim(s) *60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,45-49,53-59 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/25/2009 has been entered.

Applicant's amendment and response filed on 2/25/2009 has been received and entered into the case.

Claims 1-41, 43, 44 and 50-52 have been canceled, claim 60 has been withdrawn from consideration as being drawn to non-elected subject matter, and claims 42, 45-49, 53-59 and 61 have been considered on the merits. All arguments have been fully considered.

The claim rejection under 35 U.S.C.§102 based on Young et al. has been withdrawn due to the amendment.

The claim rejections under 35 U.S.C.§103 based on Liu et al. have been withdrawn due to the amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 42, 45-49, 53-59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (of record) in view of Snodderly et al. (2002; Invest. Ophth. Vis. Sci.), Grueterich et al. (of record) and Tseng (of record).

Young et al. teach a method and a composite graft for the treatment of conditions associated with photoreceptor loss (e.g. age-related macular degeneration), where the composite graft comprising RPE cells grown on base membrane such as amniotic membrane (abstract and p.12 lines 2-14). Young et al. also teach other types of cells including precursor to RPE cells (p.5, lines 18-19). Young et al. teach that the graft can be delivered to the subretinal space (p.17, lines 7-8). Young et al. also teach the membrane substrate can also serve as a particularly convenient delivery system for various bioactive agents (pharmaceutically active agents) such as growth factors (p.12, line 18 through p.13, line 3).

Young et al. teach that the RPE cells are delivered as an intact epithelium, an epithelial monolayer with the correct polarity, and RPE cells can be harvested as a sheet from donor eyes or alternatively, RPE cells can be proliferated in culture and secondarily grown as a monolayer (p.14).

Although Young et al. do not particularly teach the concentration of RPE cells being 16,000 – 20,000 per 4 mm^2 of amniotic membrane, this limitation is inherently met by the monolayer of RPE cells grown in culture as taught by Young et al. is considered to encompass the similar number of cells per 4 mm^2 of amniotic membrane. This is because it is known that the RPE cell density in central retina of Rhesus monkeys is

about 4000 RPE cells/mm^2 up to 7000 RPE cells/mm^2 according to Snodderly et al. (Abstract; Table 1). Therefore, it is considered that the monolayer of RPE cells of Young et al. would have the comparable amount of RPE cells per unit area and thus, meet the limitation.

With regard to the limitation of "human amniotic membrane" in claim 46, Young et al. do not particularly teach the source of the amniotic membrane. However, since Young et al. disclose the base membrane can be autologous to a patient, and it would have been obvious to a person of ordinary skill in the art to use human amniotic membrane for human patients.

With regard to the limitation in claims 57 and 58 drawn to the use of excimer laser, Young et al. do not particularly teach the limitation. However, it would have been obvious to a person of ordinary skill in the art to try excimer laser to trim and/or modify the base membrane suitable for transplantation because the excimer laser ablation technique is well known in the art to cut and reshape variety of tissues and laser treatment is commonly used for eye diseases as numerously disclosed in Young et al. (e.g. p.2, line 18). Since the technique is readily available in the art, and a person of ordinary skill in the art would recognize the technique suitable for modifying amniotic membrane, a person of ordinary skill in the art would choose to use the excimer laser technique in place of the surgical instrument for cutting the substrate for transplantation.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of

elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

The limitation of claim 58 is considered as a result of the method step in claim 57. Claim 58 contains a "wherein" clause that merely states the result of the limitations in the claim and therefore, adds nothing to the patentability or substance of the claim. Therefore, this phrase does not limit the claim. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 USPQ2d 1747 (Fed. Cir. 2001).

Young et al. do not teach the amniotic membrane being epithelially denuded.

Grueterich et al. teach the use of epithelially denuded amniotic membrane in culturing limbal epithelium (see whole document; p.64, Materials and Method).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use epithelially denuded amniotic membrane of Grueterich et al. in the method of Young et al.

The skilled artisan would have been motivated to make such a modification because both intact and epithelially denuded amniotic membrane would be suitable for

support of epithelial cell culture. Since amniotic membrane is a suitable substrate for culturing not only corneal epithelial cells as taught by Grueterich et al. but also for RPE cells, a person of ordinary skill in the art would have considered the choice of intact or denuded amniotic membrane as a routine optimization procedure to obtain optimal environment for culturing RPE cells for treating a retinal disorder.

Although Young et al. do not particularly teach the intact amniotic membrane having a basement membrane and a stroma, Tseng teaches that an amniotic membrane comprises two major components: the basement membrane and stroma (see col. 1, lines 23-24). Therefore, it would have been obvious to a person of ordinary skill in the art that the amniotic membrane of Young et al. inherently comprises basement membrane and stroma.

Young et al. do not teach a step of adding mesenchymal cells to the stroma of the amniotic membrane or the mesenchymal cells being fibroblasts.

Tseng teaches that when fibroblasts (mesenchymal cells) are grown in the stromal side of amniotic membrane, it provides an environment comparable to isolated collagen (fibroblasts are collagen-producing cells) and better cell growth in culture than a plain plastic surface.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to add fibroblasts on the stromal side of the amniotic membrane of Young et al.

The skilled artisan would have been motivated to make such a modification because Tseng teaches an advantage given by the fibroblast culture on the stromal side

of the amniotic membrane providing better cell culture environment for epithelial cells (see col. 4).

With regard to the limitation in claims 57 and 58 drawn to the use of excimer laser, Young et al. do not particularly teach the limitation. However, it would have been obvious to a person of ordinary skill in the art to try excimer laser to trim and/or modify the base membrane suitable for transplantation because the excimer laser ablation technique is well known in the art as supported by Tseng (e.g. col. 3, line 19) to cut and reshape variety of tissues and laser treatment is commonly used for eye diseases as numerously disclosed in Young et al. (e.g. p.2, line 18). Since the technique is readily available in the art, and a person of ordinary skill in the art would recognize the technique suitable for modifying amniotic membrane, a person of ordinary skill in the art would choose to use the excimer laser technique in place of the surgical instrument for cutting the substrate for transplantation.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Examiner, Art Unit 1651